

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.*
JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

DEFENDANT JANSSEN BIOTECH, INC.'S MEMORANDUM OF LAW IN SUPPORT
OF ITS MOTION FOR A PROTECTIVE ORDER CONCERNING
RELATOR'S 30(b)(6) DEPOSITION NOTICE

INTRODUCTION

On May 6, 2024, Relator Julie Long served a 30(b)(6) deposition notice on Defendant Janssen Biotech Inc. (“Janssen”), which is attached as Exhibit A. Accounting for numerous sub-topics, the Notice identifies 51 distinct topics for questioning. In response, Janssen promptly informed Relator that it intended to provide a witness to respond to most if not all of the topics identified. Janssen also notified Relator that it had significant concerns about the apparent scope of some of the topics, including topics that concerned information protected by the attorney-client privilege and topics seeking a level of detail that would not reasonably be feasible for a witness to address in a deposition. The parties discussed those concerns in the meet and confer process but were not able to resolve all issues.

During the meet and confer process, Relator identified certain topics and sub-topics as to which she would accept a written response, and Janssen informed Relator that it would provide written responses to each of those topics and sub-topics. In addition, in an attempt to avoid a dispute, Janssen informed Relator that it was also prepared to undertake an enormous amount of work and spend hundreds of thousands of dollars to prepare witnesses to address the vast majority of the information sought by each of the remaining topics. Janssen further informed Relator that it intended to provide written objections stating its positions, and Relator responded that, if Janssen “wish[ed] to propose the narrowing of a topic/subtopic... we will consider it. However, to ensure there is no confusion, absent a protective order or Relator’s agreement, we will examine Janssen’s representative(s) concerning all topics/subtopics ... as they are currently stated.” Exhibit C.

On July 22, 2024 Janssen served its Responses and Objections to Relator’s topics (attached as Exhibit B). Consistent with its discussions with Relator in the meet and confer process, Janssen agreed to provide a written response or a witness to testify on every one of the

topics noticed, subject to several important limitations. In particular, Janssen informed Relator that:

1. It would not disclose privileged information; and
2. It would provide information on the identified topics with a reasonable level of detail but could not feasibly provide the minute level of detail called for by a literal reading of certain of the topics.

Three days later, Relator responded to Janssen's objections by categorically refusing to further modify or narrow any of the topics identified, asserting that Janssen's objections were "without merit," and stating that "Plaintiff will examine Janssen's representatives concerning all topics as they are currently stated." Exhibit C.

Janssen is serving today written responses to the topics as to which Relator agreed to accept written responses. With respect to the remaining topics, Janssen informed Relator that to avoid motion practice it would provide witnesses prepared to testify as to all remaining topics. However, in light of Relator's refusal to consent to reasonable limitations on the scope of 30(b)(6) deposition questioning and Relator's demand that Janssen seek a protective order if it was not prepared to answer the questions as broadly as they are written, Janssen now seeks a protective order to set reasonable limitations to the topics set out below.

LEGAL STANDARD

Federal Rule of Civil Procedure 26(c)(1) provides that "[a] party or any person from whom discovery is sought may move for a protective order in the court where the action is pending." Thus, "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . forbidding the inquiry into certain matters, or limiting the scope of or disclosure or discovery to certain matters." *Id.* Moreover, this Court may limit discovery if it determines that:

(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;

(ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or

(iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).

Fed. R. Civ. P. 26(b)(2). Rule 26 “confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required.” *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984).

ARGUMENT

I. Relator Is Not Entitled To Privileged Information

Relator’s deposition notice includes several topics that plainly encompass privileged information. For example, Topic 4 includes:

Your knowledge and understanding concerning (a) the AKS, (b) the safe harbor regulations, and (c) the Office of Inspector General for the U.S. Department of Health and Human Services’s guidance concerning the provision of product-related services to customers.

Ex. A at 13.

Other topics also encompass confidential legal opinions, including Topic 1(p), which seeks “All actions You took to determine whether providing the [programs at issue in this case] violated the AKS and/or FCA,” and Topic 2(l) which seeks Janssen’s “belief and knowledge concerning whether providing the IOI Support to IOI Customers violated the AKS and the bases for such belief.” Janssen has confirmed that it will prepare a witness to provide non-privileged information responsive to the topics at issue, to the extent any such information exists. However, Relator refused to limit questioning to non-privileged topics in the absence of a protective order.

Relator’s insistence on seeking privileged information through these deposition topics is directly contrary to the Court’s orders over the course of discovery. As Janssen has repeatedly

informed Relator, it is not relying on privileged information in this case, and it does not intend to rely on the advice of counsel. *See* Opposition to Motion to Compel, ECF 430, at 7. Judge Saylor has confirmed on two occasions that Relator is not entitled to privileged information, and that Janssen has not waived privilege in this case. *See* ECF 303, 435. Relator has not even attempted to identify any basis to ignore those holdings during the upcoming deposition.

For these reasons, Relator has no basis to demand that Janssen prepare a witness to discuss privileged legal advice or attorney communications, and the Court should grant a protective order limiting Relator’s topics to non-privileged matters and stating that Relator may not use the noticed 30(b)(6) deposition to inquire into privileged areas.

II. Relator’s Topics Seek Extremely Detailed Information That Is Not Appropriate For A 30(b)(6) Deposition

“Rule 30(b)(6) requires the noticing party to describe the topics of examination with reasonable particularity.[.] If the noticing party does not describe the topics with sufficient particularity or if the topics are overly broad, the responding party is subject to an impossible task.” *Trustees of Bos. Univ. v. Everlight Elecs. Co.*, 2014 WL 5786492, at *3 (D. Mass. Sept. 24, 2014) (citations omitted). Indeed, “[t]o avoid liability, the noticed party must designate persons knowledgeable in the areas of inquiry listed in the notice. Accordingly, if the noticed party cannot identify the outer limits of the topics noticed, compliant designation is not feasible.” *Id.* (citations omitted). *See also* 7 Moore’s Federal Practice - Civil § 30.25 (2024) (“The court may quash a Rule 30(b)(6) deposition notice for failure to specify the areas of inquiry with reasonable particularity. Courts have explained that an overbroad Rule 30(b)(6) notice subjects the responding party to an impossible task.”). Relator’s noticed topics violate the “reasonable specificity” requirement and should be curtailed.

First, Relator has noticed numerous topics encompassing information about the 36 distinct programs and presentations that are the basis of her claims. These topics are detail-specific: although the Notice refers to them collectively as “the IOI Support and Programs,” each program has distinct content, and many have gone through multiple iterations and updates since Janssen first created the Area Business Specialist (ABS) position around the year 2000. Thus, by seeking information about every single one of the programs separately, (*compare* Topic 1 with Topic 2), the topics already entail an extreme and burdensome effort to prepare a witness.

Second, with the exception of Topic 17, Relator’s topics seek witness testimony for a period of time identified as “from the creation of the strategy to provide the IOI Support and Programs to IOI Customers to until February 19, 2016.” Practically, this translates into requests for testimony spanning at least 16 years going back to approximately 2000. The Court has previously recognized the burden associated with discovery requests seeking information from nearly 25 years ago and has declined to universally expand the scope of this case to that period on that basis. *See, e.g.*, ECF No. 320 (stating that extending discovery earlier than October 28, 2006 may violate Rule 26’s proportionality requirements). Topics that require the company to prepare a witness to provide fine details from 25 years ago about dozens of programs are unduly burdensome.

Further, many of the topics concerning the programs are phrased in a way that appears to seek a level of detail that would be impossible to provide, and which further increases the already substantial burden of preparing a witness. As just one example, Topic 1 includes eighteen subtopics, each of which asks for distinct and expansive information for each of the 36 programs at issue, as well as their “substantive equivalents” (a term Relator does not define), over a period of over sixteen years. This includes a demand for “All Your purposes and

objectives” in providing each of the programs to IOI customers (Topic 1(j)) – notwithstanding that the objective of each presentation may have been different, and that objectives may have differed from one customer to the next. Similarly, Topic 1(e) covers “The factors that were considered in determining” which of 12 physician practices at issue in this stage of the litigation received each of the 36 programs at issue, despite the fact that the programs at issue were presented to those physician practices numerous times over many years and that numerous individuals were involved in the determination of when to provide those programs. No witness could reasonably provide this level of detail, or the similar level of detail sought by other Topics concerning the 36 programs at issue.

In addition to topics spanning the 36 programs at issue, many of Relator’s deposition topics are unduly burdensome and overly expansive because they seek extremely detailed information about Janssen’s business policies and programs, including each iteration or development in those programs, again over a period spanning well over a decade. For instance, Topic 13 seeks testimony about “[t]he development and approval of the strategy to provide the IOI Support and Programs to IOI Customers, including the approval(s) to continue engaging in the strategy,”¹ for a period spanning approximately twenty years. This expansive topic is impossible to cabin as written: there is no way that Janssen can reasonably determine what specific “strategies” are encompassed, what departments and individuals were involved in those purported strategies, or which of the 36 programs are implicated. (As Relator is aware, the strategic considerations for each of those presentations are distinct, and they may have changed

¹ This quote reflects limited changes by Relator in the meet and confer process, which are not reflected in Exhibit A.

over time). Again, no witness could possibly be prepared to testify in comprehensive detail about the issues implicated in this topic.

Similarly, Topic 11 seeks testimony about “Your compliance policy and/or guidance document (and equivalents thereof) concerning the topics of: providing consulting and/or services to customers [], providing reimbursement information and services to customers [], and/or providing educational support and/or programs to customers [],” for any time during the period from 2001 to February 2020. The Topic specifically identifies eleven examples of the types of policies intended, which on their own total 320 pages. On top of that, Relator’s demand for all versions of the policies and all “equivalents” for nearly twenty years makes this topic impossible to prepare a witness to address.

The following topics are all so vague and overbroad as to make it impossible to fully prepare a witness.

No.	Topic
1	“For each Program (or its substantive equivalent), the following information:” [see Ex. A for full set of eighteen subtopics concerning the 36 programs at issue]
2(b)	“For the IOI Support as a whole, the following information: . . . The factors that were considered in determining which physician practices received the IOI Support.”
2(c)	“For the IOI Support as a whole, the following information: . . . All Your purposes and objectives in providing the IOI Support to IOI Customers.”
5	“The actions You took to train Your employees who were responsible for evaluating the legality of providing the IOI Support concerning conduct prohibited by the AKS, including the provision of services that have independent value to customers.”
11	“Your compliance policy and/or guidance document (and equivalents thereof) concerning the topics of: providing consulting and/or services to customers [], providing reimbursement information and services to customers [], and/or providing educational support and/or programs to customers [].”
13	“The development and approval of the strategy to provide the IOI Support and Programs to IOI Customers, including the approval(s) to continue engaging in the strategy.”
14	“An explanation of the infusion business model, IOI business model, and/or Remicade business model that You promoted to IOI Customers.” ²

² This quote reflects limited changes by Relator in the meet and confer process, which are not reflected in Exhibit A.

17	“The corporate organization and responsibilities of the departments, groups, and teams (such as sales, marketing, legal, compliance, regulatory, analytics, sales training, and finance) who had significant involvement in the strategy to provide the IOI Support to IOI Customers.” ³
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Janssen informed Relator that it will prepare a witness to testify on all of these topics, but that it cannot feasibly prepare a witness to testify at a high level of detail about each and every fact that might plausibly fall within their scope. When Janssen raised these concerns, Relator refused to further cabin these topics in any way.

“A corporate designee is ‘not expected to be a corporate encyclopedia,’ able to answer anything and everything about the company.” *One World, LLC v. Manolakos*, 2024 WL 3458347, at *3 (D. Mass. July 18, 2024) (citation omitted). For this reason, “[a]lthough Rule 30(b)(6) requires a designated witness to thoroughly educate him or herself on the noticed topic, there must be a limit to the specificity of the information the deponent can reasonably be expected to provide.” *U.S. ex rel Fago v. M & T Mort. Corp.*, 235 F.R.D. 11 (D.D.C. 2006) (finding that witness could not reasonably testify about topics seeking specific information about numerous separate identified loans). Further, topics seeking testimony on matters that are not “reasonably available” to the party being deposed may be unduly burdensome and disproportional to the needs of the case and are outside the scope of discovery allowed under Federal Rule of Civil Procedure 26. *See generally Sec. & Exch. Comm’n v. Navellier & Assocs., Inc.*, 2019 WL 688164, at *1 (D. Mass. Feb. 19, 2019) (noting that Rule 26 operates to limit the discovery that can be sought under Rule 30(b)(6)).

³ In the meet and confer process, Relator agreed to limit the date range for this topic to the six year period from 2010 until February 2016. Relator has stated that she will not agree to further limitations on this topic without a protective order.

Moreover, as Relator is aware, the extreme breadth guarantees that much of the information covered by the topics will be duplicative of the relevant discovery that Relator has already received. To identify just a few examples:

- Topic 1 seeks detailed information about the programs at issue. But Janssen has already produced copies of every one of those programs, including different versions that existed over time. Relator has also received the PRC approval records reflecting the review and approval of those presentations by compliance personnel, and expansive database files that include all available information about when and to whom those presentations were provided. Further, Relator has taken 15 depositions, including depositions of the individuals who were “substantially involved” in the development, approval, and presentation of those presentations from the Marketing, Compliance, and Law departments.
- Topic 2(c) seeks all “purposes and objectives” in providing the presentations at issue. However, Janssen has already responded at length to Relator’s broad interrogatories on this topic, which include Interrogatory No. 1: “State all the reasons why you helped physicians open an IOI,” and Interrogatory No. 6: “State all the reasons why you had ABSs (including Plaintiff) or any Outside Consultant provide the [programs at issue].” Relator has also had further opportunities to discuss the goals of the individual programs in the course of depositions.
- Topic 11 encompasses Janssen’s compliance policies and guidance documents. However, those policies have already been produced to Relator and speak for themselves. And, again, Relator has taken the depositions of the Compliance and Legal personnel who had authority over those policies and has asked questions concerning their development and contents.

In sum, Relator appears to intend for Janssen to provide a witness to review the thousands of documents that it has produced and then respond to detailed questions about those documents on demand. But this is not the purpose of a 30(b)(6) deposition. Caselaw in this Circuit is clear that a party has no obligation to prepare a witness simply to present or summarize evidence that has already been produced in other forms. *See, e.g., Ameristar Jet Charter, Inc. v. Signal Composites, Inc.*, 244 F.3d 189, 193 (1st Cir. 2001) (holding that if a party “presents no evidence that any new, relevant information will be obtained if it is permitted to take the depositions,” the court “will not allow [a party] to go on a ‘fishing expedition,’ with the mere ‘hope’ that it will obtain such information.”).

Confronted with similarly expansive and burdensome deposition topics, courts have frequently affirmed that a party need only prepare a witness to answer general questions concerning high level corporate records, policies, and practices, rather than responding in detail on all particulars. *See, e.g., McPherson v. Canon Bus. Sols., Inc.*, 2014 WL 654573, at *9 (D.N.J. Feb. 20, 2014) (authorizing limited 30(b)(6) questioning about hiring policies and practices, but prohibiting questioning about individual decisions within those policies); *W Holding Co. v. Chartis Ins. Co. of Puerto Rico*, 300 F.R.D. 43, 46 (D.P.R. 2014) (striking topics seeking testimony on “all policies and regulations” as “so broad as to be meaningless”); *see also Burdine v. Covidien, Inc.*, 2011 WL 613247, at *3 (E.D. Tenn. Feb. 11, 2011) (denying as moot a motion to compel a 30(b)(6) witness to testify, when defendant agreed to “produc[e] a witness to testify generally about this topic, but state[d] it ‘cannot represent that any one person will possess information’ ‘regarding each and every job duty and work assignment performed by Plaintiff ever.’”). Because Janssen cannot reasonably provide a witness to testify at the level of detail sought by Plaintiff, the Court should issue a protective order stating that Janssen may

provide a witness to testify about all of the programs at issue collectively, rather than providing witnesses to address those programs on an individual basis, and that Janssen may discuss corporate records, policies, and practices on a general basis, and is not required to prepare a witness to testify as to every single record, policy, or practice that falls within the topics identified.

CONCLUSION

For the foregoing reasons, the Court should enter a protective order holding that (1) Relator may not seek information protected by the attorney-client privilege or work product protection; and (2) Janssen may provide a witness to testify about the programs at issue collectively, rather than on an individual basis, and to testify about corporate records, policies, and practices on a general basis, rather than as to every single record, policy, or practice that falls within the topics identified.

Dated: August 2, 2024

Respectfully Submitted,

/s/ Jason C. Raofield

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CERTIFICATE OF SERVICE

I hereby certify on this 2nd day of August, 2024, that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Bradley Markano

Bradley Markano (admitted *pro hac vice*)